

REMARKS

I. Status of the Application

Claims 1 – 4 are presently pending in the application. Claims 1 – 4 stand rejected under 35 U. S. C. § 102(e) as being anticipated by Burg (U.S. Patent Application Ser. No. 09/879,360). Claims 1 – 4 stand rejected under 35 U. S. C. § 102(b) as being anticipated by Walter et al. (U. S. Patent No. 5,863,297). Claims 1 – 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burg in view of Hammarström et al. (U.S. Patent No. 5,098,891) or Hammarström et al. (U.S. Patent No. 5,418,221). Claims 1 – 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Walter et al. (US Patent No. 5,863,297) in view of Hammarström et al. ('891) or Hammarström et al. ('221).

Claims 1 – 4 have been cancelled without prejudice to the filing of any appropriate continuation application. Applicants respectfully submit that the amendments presented herein are supported by the specification and are not new matter.

Support for the claims directed to applying tooth germ cells to a biodegradable polymer scaffold is found in the specification at least at page 3 lines 21 – 23 and at page 13 lines 12 – 16. At page 3, the specification states that dissociated tooth germ may become mature through the techniques of tissue engineering. At page 13 of the application, dissociated enamel and pulp cells, which are tooth germ, are obtained and the cells are seeded onto a scaffold. At page 9 lines 5 – 12, the specification states that the enamel and pulp organ tissues were used from the unerupted molars of six-month old pigs. In addition, at page 8 lines 11 – 12, the specification reads, “tissues were allowed to develop inside the host animals....” The enamel and pulp organ tissues of six-month old pigs are still classified as tooth germ cells.

Support for allowing the tooth germ cells to develop into a tooth for implanting can be found at least at page 13 lines 14 – 15 of the application. The relevant part reads, “the cell/polymer construct was implanted into the omentum of a nude rat host and allowed to develop for 20 weeks.”

Forming a tooth mold, wherein the biodegradable polymer scaffold is formed in the tooth mold is supported at page 10 line 29 to page 11 line 3. The biodegradable polymer scaffold in the shape of a tooth and in the shape of a human tooth is supported at page 5 line 10, and page 5 lines 14 – 15, respectively.

Support for forming a biodegradable polymer scaffold can be found at page 7 lines 4 -14. Support for implanting the scaffold into a host animal can be found at page 8 lines 9 – 10.

Preparing a tooth mold wherein the biodegradable polymer scaffold is formed in the tooth mold is supported at page 6 line 25 to page 7 line 14.

Support for tooth germ cells comprising cells dissociated from an enamel organ and a pulp organ is found at page 9 lines 5 - 12. The specification states that the enamel and pulp organ tissues were used from the unerupted molars of six-month old pigs. The enamel and pulp organ tissues of six-month old pigs are classified as tooth germ cells.

Support for the tooth germ cells being mammalian is found at page 10, line 12 because pigs are mammalian. This is also where support for the tooth germ cells being porcine is found.

Support for the tooth germs cells being from an enamel organ, a pulp organ, and from tissue cultures derived from tooth tissues is found at page 5, lines 13 – 14.

Support for the scaffold being implanted into an omentum of a host animal or a rat can be found at page 12, lines 20 – 22.

The tooth germ cells being applied with between 20 to 50 million cells per square inch is supported at page 15 lines 2 – 3.

Support for the biodegradable polymer scaffold being selected from poly(lactide), poly(glycolide), and poly(L-lactide-co-glycolide), is found at page 6 in Table 2.

The tooth germ cells being allowed to attach to the scaffold for at least one hour prior to implanting is supported at page 8, lines 8 – 9.

The biodegradable polymer scaffold being coated in collagen prior to applying is supported at page 9 lines 15 – 16.

Applicants respectfully request reconsideration of the application and allowance of claims 5 – 33.

II. Rejection of Claims 1 – 4 Under 35 U.S.C. § 112

On page 2, paragraphs 3 – 5 of this Office Action, the Examiner rejected claim 1 for not providing antecedent basis for “polymer fibers.” Claim 4 was rejected for reciting only a future intended use. In addition, claims 2 and 3 were rejected for their dependence from claim 1. Claims 1 – 4 have been cancelled. Accordingly, Applicants respectfully request withdrawal of the rejections.

III. Claims 1 – 4 Are Not Anticipated by Burg

On page 3, paragraph 8 of the Office Action the Examiner rejected claims 1 – 4 as being anticipated by Burg. The Examiner asserts that Burg describes a method of making new dental tissue that uses a porous matrix made from a biocompatible biodegradable polymer. The Examiner also asserts that Burg anticipates the claims because claim 1 does not require the

presence of tooth bud cells. Applicant's respectfully traverse the Examiner's rejections based on the newly submitted claims. Claims 1 – 4 have been cancelled and the new claims require the presence of tooth germ cells. Accordingly, Applicants respectfully request withdrawal of this anticipation rejection.

IV. Claims 1 – 4 Are Not Anticipated by Walter et al.

On page 4, paragraph 9 of the Office Action, the Examiner rejected claims 1 – 4 as being anticipated by Walter et al. The Examiner asserts that Walter et al. discloses a moldable implant material used to grow new dental tissue. The Examiner asserts that the method involves a porous matrix of biodegradable polymer that would inherently have the same properties of those disclosed in the application. In addition, the Examiner also asserts that Walter et al. also anticipates the claims because claim 1 does not require the presence of tooth bud cells. Applicants respectfully traverse the Examiner's rejection based on the newly presented claims. Claims 1 – 4 have been cancelled, and the new claims require the presence of tooth germ cells. Accordingly, Applicants respectfully request withdrawal of this anticipation rejection.

V. Claims 1 – 4 Are Not Obvious Over Burg in View of Hammarström et al. ('221) or Hammarström et al. ('891)

At page 5, paragraph 11 of the present office action, claims 1 – 4 stand rejected as being unpatentable over Burg in view of Hammarström et al. ('891) or Hammarström et al. ('221). The Examiner states that Burg teaches a method of using a porous polymer matrix as a scaffold to grow tissue. The Examiner states that Hammarström et al. ('891) and Hammarström et al. ('221) disclose methods for using the cells defined in claim 2 to grow new tooth tissue. The Examiner asserts that it would have been obvious to one of skill in the art to use the cells of

Hammarström et al. ('891) or Hammarström et al. ('221) in the invention of Burg. The Examiner further states that an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding in Burg with the "cells" of Hammarström et al. ('891) or Hammarström et al. ('221). Applicants respectfully traverse the Examiner's rejection as to the newly presented claims.

Applicants' claims are directed to a method of generating a dental implant using tooth germ cells. The claimed method includes applying tooth germ cells onto a biodegradable polymer scaffold.

Burg does not teach or suggest the use of tooth germ cells. Instead, Burg teaches the use of a biodegradable support construct and a gel matrix made of a biocompatible material. The Examiner has chosen to modify Burg with the teachings of Hammarström et al. ('891) or Hammarström et al. ('221). Neither Hammarström et al. ('891) nor Hammarström et al. ('221), however, teaches or suggests the use of tooth germ cells and accordingly, each fails to cure the deficiencies of Burg. Hammarström et al. ('891) and Hammarström et al. ('221) teach the use of a composition of a **cell extract** made from the enamel matrix, dentin, odontoblasts, and dental papille and not tooth germ cells. For example, see col. 5, lines 59 – 68 of Hammarström et al. ('891) in which, "0.3 g of matrix (protein contents 27+4%) were slurried in 3 ml of 0.9%NaCl and homogenized under cooling with ice.... The homogenate was then freeze dried." For another example, see col. 5, lines 26 – 41 of Hammarström et al. ('221) in which the "tooth germs freed of the enamel organ are scraped to isolate and recover the desired enamel matrix, a semi-solid white mass being obtained which is homogenized with water to form a whipped cream-like consistency." From the specifications of Hammarström et al. ('891) and Hammarström et al. ('221) it is clear that they teach the use of a cell extract or homogenate and

not tooth germ cells. The Examiner's combination of Burg with Hammarström et al. ('891) or Hammarström et al. ('221) therefore fails to teach or suggest all of the limitations of Applicants' claimed subject matter.

Additionally, Applicants respectfully submit that there is no motivation to combine Burg with Hammarström et al. ('891) and Hammarström et al. ('221). The Examiner's stated motivation for modifying the method of generating a dental implant of Burg with Hammarström et al. ('891) and Hammarström et al. ('221) is that an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding of Burg with the cells of Hammarström et al. ('891) and Hammarström et al. ('221). As Applicants stated previously, neither Hammarström et al. ('891) nor Hammarström et al. ('221) teach the use of tooth germ cells. Therefore, one of ordinary skill in the art would not be motivated to combine Burg with Hammarström et al. ('891) or Hammarström et al. ('221) in the way the Examiner suggested to arrive at Applicants claimed method including the use of tooth germ cells. Accordingly, Applicants traverse this basis for rejection.

In view of the above, Applicants respectfully request withdrawal of the obviousness rejection of the claims under 35 U.S.C. § 103(a).

VI. Claims 1 – 4 Are Not Obvious Over Walter et al. In View of Hammarström et al. ('891) or Hammarström et al. ('221)

At page 6, paragraph 12 of the present office action, claims 1 – 4 stand rejected as being unpatentable over Walter et al. in view of Hammarström et al. ('891) or Hammarström et al. ('221). The Examiner states that Walter et al. teach the use of a porous polymer matrix as a scaffold to grow tissue. The Examiner states that Hammarström et al. ('891) and Hammarström et al. ('221) disclose methods for using cells defined in claim 2 to grow new tooth tissue. The

Examiner states that it would have been obvious to one of skill in the art to use the cells of Hammarström et al. ('891) or Hammarström et al. ('221) with the invention of Walter et al. The Examiner further states an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding in Walter et al. with the "cells" of Hammarström et al. ('891) or Hammarström et al. ('221). Applicants respectfully traverse the Examiner's rejection as to the newly presented claims.

Applicants' claims are directed to a method of generating a dental implant by applying tooth germ cells onto a biodegradable polymer scaffold.

Walter et al. do not teach or suggest the use of tooth germ cells. Instead, Walter et al. teach the use of a biodegradable support construct and a gel matrix made of a biocompatible material. The Examiner has chosen to modify Walter et al. with the teachings of Hammarström et al. ('891) or Hammarström et al. ('221). Neither Hammarström et al. ('891) nor Hammarström et al. ('221), however, teaches or suggests the use of tooth germ cells and accordingly, each fails to cure the deficiencies of Walter et al. Hammarström et al. ('891) and Hammarström et al. ('221) both teach the use of a composition of a **cell extract** made from the enamel matrix, dentin, odontoblasts, and dental papille. For example, see col. 5, lines 59 – 68 of Hammarström et al. ('891) in which, "0.3 g of matrix (protein contents 27+4%) were slurried in 3 ml of 0.9%NaCl and homogenized under cooling with ice. . . . The homogenate was then freeze dried." For another example, see col. 5, lines 26 – 41 of Hammarström et al. ('221) in which the "tooth germs freed of the enamel organ are scraped to isolate and recover the desired enamel matrix, a semi-solid white mass being obtained which is homogenized with water to form a whipped cream-like consistency." From the specifications of Hammarström et al. ('891) and Hammarström et al. ('221) it is clear that they teach the use of a cell extract or homogenate and

not tooth germ cells. The Examiner's combination of Walter et al. with Hammarström et al. ('891) or Hammarström et al. ('221), therefore, fails to teach or suggest all of the limitations of Applicants' claimed subject matter.

Additionally, Applicants respectfully submit that there is no motivation to combine Walter et al. with Hammarström et al. ('891) and Hammarström et al. ('221). The Examiner's stated motivation for modifying the method of generating a dental implant of Walter et al. with Hammarström et al. ('891) and Hammarström et al. ('221) is that an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding of Walter et al. with the cells of Hammarström et al. ('891) and Hammarström et al. ('221). As Applicants stated previously, neither Hammarström et al. ('891) nor Hammarström et al. ('221) teach the use of tooth germ cells. Therefore, one of ordinary skill in the art would not be motivated to combine Walter et al. with Hammarström et al. ('891) or Hammarström et al. ('221) in the way the Examiner suggested to arrive at Applicants claimed method including the use of tooth germ cells. Accordingly, Applicants traverse this basis for rejection.

Applicants respectfully request withdrawal of the obviousness rejection of the claims under 35 U.S.C. § 103(a) as to the newly presented claims.


VII. Conclusion

Applicants respectfully request reconsideration of the pending claims in view of the foregoing remarks. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

The Commissioner is authorized to apply any charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: May 15, 2003



John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
(617) 720-9600